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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/493,803	01/28/00	GOOD	A AGZ-002

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/0212

EXAMINER

KRUSE, D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/493,803	Applicant(s) GOOD, ALLEN G.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,26,37,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,26,37,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claim 7,8,26,37, 38 and 39 in Paper No. 7, filed 24 January 2001 is acknowledged.
2. Claims 1-6,9-25,27-36 and 40-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed 24 January 2001.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.
4. The Abstract is objected to as not being directed to the subject matter of the elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7, 8, 26, and 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for directing root-specific expression of a target gene in a plant with the btg-26 promoter of SEQ ID NO: 1 wherein said promoter is osmotically regulated and a seed comprising said promoter, does not reasonably provide enablement for a method for directing root-specific

expression of a target gene in a plant with any root-specific promoter and wherein said root-specific promoter is environmentally or developmentally regulated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method for directing root-specific expression of a target gene in a plant comprising transforming a plant cell such that root-specific expression of a target gene occurs, and a seed transformed by said method.

Applicant teaches a method for directing root-specific expression of a target gene in a plant with the *btg-26* promoter (SEQ ID NO: 1) (page 40) and Applicant teaches that said promoter is osmotically regulated in a transgenic plant (pages 41-42).

Applicant does not teach a method for directing root-specific expression of a target gene in a plant by transforming a plant cell with any other promoter sequence such that root-specific expression of a target gene occurs and wherein said promoter sequence is environmentally or developmentally regulated.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

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The state of the art for isolation of promoters having specific tissue specificity and/or specific regulation is unpredictable. In addition, the controlling regions of such multifunctional promoters reside in separate areas of the sequence. Minor changes in the length or sequence of a promoter can cause a large change in the promoter's activity, specificity or regulation (see Montgomery *et al.* Proc. Natl. Acad. Sci., USA, 1993, 90:5939-5943, specifically Figures 2 and 3) and thus one of ordinary skill in the art requires extensive guidance as to what sequences are required for tissue specificity and specific regulation in addition to promoter activity. The state of the art for modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. The specific effects of given promoters, leaders, DNA sequences, and terminator sequences on gene expression in transformed plants can not be anticipated reliably and must be determined empirically (Koziel *et al.*, Plant Mol. Biol. 32:393-405, 1996, abstract, pp.402-403).

Applicant has not taught a method for directing root-specific expression of a target gene in a plant comprising transforming a plant cell with a polynucleotide sequence that is environmentally or developmentally regulated other than that encoding the promoter *btg-26*, such that root-specific expression of a target gene occurs. Hence, it would require undue experimentation by one of ordinary skill in the art to isolate all root-specific promoter sequences, transform plants with said promoter sequences and select those promoter sequences that are root-specific and/or that are environmentally

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or developmentally regulated in order to practice Applicant's invention as broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 8 and 38 are rejected as indefinite for being in improper Markush format.

The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h). Specifically the phrases "proteins or enzymes" at line 5, and "uptake or utilization" at line 6, render the Markush language improper. In addition, the limitation "gene" in the preamble is singular while the listed limitations in the Markush group "genes" are plural. Appropriate correction is required.

9. Claims 26 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if Applicant is claiming an additional regulatory element or if the "genetic regulatory element" of the parent claim is being further limited. In addition, is unclear what Applicant intends to encompass by "environmentally or developmentally regulated". Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 7, 8, 26 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Dixon *et al* (U.S. Patent 5,750,399).

Applicant claims a method for directing root-specific expression of a target gene in a plant comprising transforming a plant cell such that root-specific expression of a target gene occurs, said expression being environmentally or developmentally regulated.

Dixon discloses ifrL^{ong} and $\text{ifrS}^{\text{hort}}$ promoter constructs that are root-specific in alfalfa (column 10 last paragraph to column 11 first paragraph) and can be elicited by environmental factors (see Figure 5). In addition, Dixon claims a plant cell (see claim 15) and a method of expressing in a plant cell (see claim 28) wherein a recombinant nucleic acid molecule comprises an isolated DNA segment comprising a portion of (an) isoflavone reductase promoter region capable of directing the developmental or elicitor/infection-induced expression of an operably linked structural gene. Hence, all of the claim limitations were previously disclosed by Dixon.

12. Claims 7, 9, 26 and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Good *et al* (U.S. Patent 6,084,153).

Applicant's claims are discussed above.

Good discloses a genetic construct comprising the *btg-26* promoter operably linked to a heterologous nucleic acid sequence (see Figure 7B) and a method of producing a plant cell with said construct wherein the promoter is inducible under osmotic stress conditions (see column 11, lines 46-57). Good also teaches seed comprising said genetic construct (see Example 3, column 12).

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As Applicant teaches a genetic construct comprising the btg-26 promoter operably linked to a heterologous gene, one of ordinary skill in the art would recognize that the construct of Good and that of Applicant would inherently have identical root-specific properties. The sequence of SEQ ID NO: 1 of Good and SEQ ID NO: 1 of Applicant are identical. Applicant has not taught the specific fragment(s) of SEQ ID NO: 1 that would be required to get root-specific expression of a heterologous sequence. The construct of Good would inherently possess root-specific expression activity and be osmotically regulated. As Good has taught a method of transforming plants with the btg-26 promoter operably linked to a heterologous gene and seed derived therefrom, all of the claim limitations were previously disclosed by Good.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 7, 8, 26 and 37-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S.

Patent No. 6,084,153. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because they are both directed to a method of transforming a plant with a construct comprising the btg-26 promoter operably linked to a heterologous nucleic acid sequence and transgenic seed comprising said construct.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Paula Hutzell can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Yolanda Vines whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

David H. Kruse, Ph.D.
7 February 2001